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September 25, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0339

The American Association of Blood Banks (AABB) submits the following written comments to supplement our oral statement presented during the September 14, 1998 Public Meeting on Section 406(b) of the FDA Modernization Act of 1997. The AABB is the professional society for over 8,500 individuals involved in blood banking and transfusion medicine. The Association also represents more than 2,200 institutional members, including community and Red Cross blood collection centers, hospital based blood banks and transfusion services, as they collect, process, distribute and transfuse blood and blood components and hematopoietic stem cells. Our members are responsible for virtually all of the blood collected and more than 80 percent of the blood transfused in this country.

For over 50 years, the AABB's highest priority has been to maintain and enhance the safety of the nation's blood supply. As a voluntary standard-setting and accrediting association, the AABB works hard in a number of areas to ensure a safe, readily available blood supply. We also recognize the critical role the Food and Drug Administration (FDA) plays in protecting consumer health by regulating blood products. We believe it is essential that the FDA and the private sector, including professional organizations such as the AABB, work together in reaching our common goal – providing Americans access to a safe, available blood supply. Neither the public nor private sectors can meet this goal alone; rather, there must be a healthy balance and interaction between these interested parties.

We commend FDA for holding its recent series of meetings (including this one) regarding Section 406(b) of the FDA Modernization Act (FDAMA), and have welcomed the opportunity to provide AABB's and the blood industry's perspective on how best to meet objectives of the Act. Through meetings such as this as well as valuable workshops the Center for Biologics Evaluation and Research (CBER) has held with regulated parties, FDA has demonstrated an increased interest in communicating with the blood banking community. We are hopeful that the Agency will continue to build upon these communications to enhance patient access to needed blood-related products.

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While developing its plan for compliance with FDAMA, the FDA will hear from a wide range of interested consumer, health professional and industry representatives suggestions to protect consumer health. While many of us will have similar or complementary recommendations, the Agency must be careful not to treat all regulated industries identically. In developing and implementing policies relating to blood products, the unique nature of this industry must be considered. A safe, available blood supply is clearly a national health priority. Unlike other FDA-regulated products that reach only limited populations, blood and blood-related products are needed for an extremely broad array of therapies and large, diverse populations. In addition, although there are relatively few types of blood-related products produced, the exact same products are produced in multiple locations across the country. Moreover, many of these “production” locations, including community blood banks and hospitals, are quite different from the production facilities operated by manufacturers of other pharmaceuticals.

Adequate Resources

Before addressing particular consumer health protection functions, we would like to stress the need for adequate agency resources. In order for consumers to have access to safe and effective products, the FDA must have sufficient resources to fulfill its many responsibilities. The AABB is concerned that as Members of Congress and others turn increasingly to user fees to provide needed dollars that non-user fee programs may be neglected and not receive necessary funding. We do not believe that user fees are an appropriate means of funding FDA’s blood-related activities. User fees may be appropriate for pharmaceutical companies willing to pay for faster license application reviews. Faster approval allows these firms to increase profits by bringing their products to market sooner. However, as a policy matter, the AABB is convinced that user fees are inappropriate for blood collected for transfusion. The nation’s blood supply is a shared resource that is available to all Americans. Blood used for transfusion is drawn from altruistic individuals and processed by not-for-profit organizations. With regard to blood and plasma collected for further manufacture, the plasma is essentially a raw material that is used to manufacture biological products that are currently subject to user fee requirements.

We recognize that, like the rest of the government, the FDA is under considerable fiscal pressures. One way of alleviating some of these pressures may be to increase agency collaboration with private organizations. Experienced private entities, including professional societies and voluntary standard-setting or accrediting organizations, can provide valuable services to the agency, often at a lesser cost than it would take for the agency itself to carry out similar tasks. We urge FDA to explore such potentially cost-saving collaborative arrangements with third parties.

Collaboration with Third Parties

The AABB feels strongly that the FDA should rely to a greater extent on third-party standard-setting and accreditation organizations.

Standard Setting:

Since 1957, the AABB has issued standards for voluntary compliance in blood and blood component collection, processing and transfusion. In addition, in 1991, the AABB published its first standards for the collection, processing and transplantation of hematopoietic progenitor stem cells. AABB's standards are refined and expanded every 18 months through a deliberative process that combines elements of scientific peer review, clinical experience, expert advice and regulatory analysis.

AABB members with expertise in the field and an ability to develop medical-technical policy serve on a Standards Committee. The committee's goal is to obtain and consider the widest range of relevant medical scientific and practice data in order to ascertain and reflect the best available medical practices in the field. Liaisons from government agencies and other medical organizations provide additional expertise and commentary. In addition, two public representatives representing patient and blood donor interests serve on the committee. Draft standards are distributed to all AABB members in AABB publications and made available to the public-at-large for comment.

The AABB is pleased to note that in developing its new regulatory framework for tissue products the FDA has expressed a desire to work with private organizations in establishing national standards for the collection and use of hematopoietic progenitor stem cells. Recognizing that voluntary organizations, such as the AABB, have considerable experience in standard setting, the agency has proposed a system under which it will review and adopt industry-specific standards developed by professional societies. The AABB welcomes the opportunity to participate in this public-private effort and is coordinating with other professional societies to develop uniform consensus standards for HPCs. We urge the FDA to engage third-party organizations in similar standard-setting endeavors for blood products.

We also believe that the best model for blood and HPC standards is one that is similar to the ISO 9000 model, which was developed by the International Organization for Standardization. Using this model, organizations can incorporate a prospective comprehensive quality management program into the standards-writing process. We are also attracted to this model because of its universal appeal; ISO 9000 standards are being applied throughout Europe.

Accreditation Programs:

Increased cooperation with private accrediting bodies could also help FDA become more efficient and reduce burdens on accredited facilities, without compromising the public's safety. The AABB Accreditation Program strives to improve the quality and safety of blood banking practices, including collecting, processing, testing, distributing and administering blood and blood products. The accreditation program assesses the quality and operational systems in place within AABB member facilities. The basis for

assessment includes compliance with AABB *Standards*, applicable sections of the Code of Federal Regulations and federal guidance documents. This independent assessment of a facility's operations helps the facility to prepare for other inspections and serves as a valuable tool to improve both compliance and operations. Accreditation is granted for a variety of activities, including blood center, transfusion service and hematopoietic progenitor cell activities. As of January 1998, the AABB *Standards for Blood Banks and Transfusion Services* require facilities to implement and monitor a quality program.

A federal model for government cooperation with third-party assessors already exists in the Health Care Financing Administration under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). HCFA grants deemed status to certain third-party organizations with accreditation programs that the agency determines provide reasonable assurance that the facilities accredited by them meet or exceed the conditions required by CLIA. HCFA has granted deemed status to AABB's accreditation program, including our new quality and operational systems assessment program. We strongly recommend that FDA consider adopting an accreditation program similar to HCFA's, thus allowing the agency to take advantage of the expertise of private accrediting organizations and eliminating unnecessarily duplicative inspections of blood-related facilities.

Increased Emphasis on Non-regulatory Activities

In its meeting notice, the FDA also asks for input regarding areas in which it should place an increased emphasis on non-regulatory activities. As a general matter, the AABB believes that the agency should first focus its regulatory energies on areas involving the greatest risk. On the other hand, supplements for established products whose risks are understood should be subject to less agency scrutiny than new products with unknown or greater risks.

For some time, the blood industry has had concerns about FDA's review of modifications or changes to approved blood product and license applications. The AABB is pleased that the agency and CBER have taken steps to improve these reviews.

As to non-regulatory functions, the AABB urges the FDA to do more to assist manufacturers in the design and implementation of research and testing protocols. More dialogue between industry and the FDA is also needed in the area of post-approval experience with products. Industry should be encouraged to report on their experiences through implementation of simpler, easier and non-duplicative agency reporting mechanisms.

One possible avenue for agency-industry communications regarding the application review and post-approval review processes is FDA workshops with industry. In the blood industry, we have found these workshops most beneficial in providing an opportunity for professionals, industry, the agency and other interested parties to share information and engage in worthwhile dialogues. During similar workshops, the FDA

should provide information about the specific review criteria the agency considers in assessing product applications.

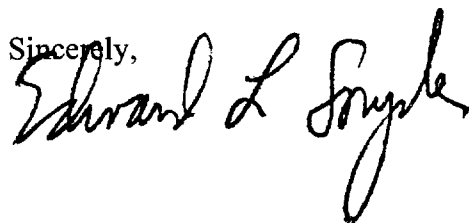
Consumer Education

Finally, we would like to stress the importance of consumer education.

The AABB believes, particularly in the area of blood-related products, that Agency efforts to educate consumers about the product risks and benefits are of the utmost importance. Even though blood-related products are some of the most widely used FDA-regulated products, they are also among the most misunderstood by the public. These misunderstandings have led to decreases in blood donations as well as some unjustified fears about risks associated with blood products. Working with industry and professionals, the FDA should devote significant staff and resources to improving the public's understanding of the blood supply, the importance of blood donation and the role of blood-related products in improving patients' health. It is critical that Agency education effort provide a complete story, focusing on the general safety of the blood supply, as well as possible risks or safety concerns.

The AABB appreciates the opportunity to share our views regarding the FDA's role in protecting consumer health. We look forward to continuing to work with the agency and other interested parties to ensure Americans have timely access to safe blood-related products. Should you have any questions concerning our comments, please feel free to contact me or Kay R. Gregory, MS, MT(ASCP)SBB, Director, Regulatory Affairs at (301) 215-6522 or by e-mail at kayg@aabb.org.

Sincerely,

A handwritten signature in black ink, reading "Edward L. Snyder". The signature is fluid and cursive, with the first name "Edward" being the most prominent part.

Edward L. Snyder
President